Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

13031

0 - FRONT

To: Lori Love@[redacted]N@FDA.CFSAN
From: <LAL@BF[redacted]>
Certify: N
Subject: Ephedrine - Herbalife
Date: Monday, August 3, 1998 at 9:41:23 am EDT
Attached: None

ARMS 13031

*** Forwarding note from SMTP --BFD 07/31/98 08:39 ***

Received: from vm.cfsan.fda.gov by VM.CFSAN.FDA.GOV (IBM VM SMTP V2R2)
with BSMTP id 2425; Fri, 31 Jul 98 08:39:30 EDT
Message-Id: <19980731.083930.M2B@BFD>
Date: 31 Jul 1998 08:39:30 EDT
From: <M2B@BFD>
To: <LAL@BFD>
Subject: Ephedrine - Herbalife

AER for you.

*** Forwarding note from M2B --BFD 07/31/98 08:36 ***
** Original Mime format message converted for OV by OFSMIME **
From: [redacted]
To: m2b@fdacf.ssw.dhhs.gov
Date: Wed, 29 Jul 1998 08:19:14 -0500
Subject: Ephedrine - Herbalife

Original [redacted] Header:
Received: from [redacted] by VM.CFSAN.FDA.GOV (IBM VM SMTP V2R2)
with TCP; Wed, 29 Jul 98 09:20:12 EDT
Received: [redacted] with Internet Mail Service [redacted]
id [redacted]; Wed, 29 Jul 1998 08:16:35 -0500
Message-ID:
[redacted]
From: [redacted]
To: m2b@fdacf.ssw.dhhs.gov
Subject: Ephedrine - Herbalife
Date: Wed, 29 Jul 1998 08:19:14 -0500
MIME-Version: 1.0
X-Mailer: Internet Mail Service [redacted]
Content-Type: text/plain;
[redacted]

Dear Ms. Binzer,

Back on May 28th I consumed a sample package of the diet supplement Herbalife. I followed the instructions given by a friend who was selling — (1) & (2)

it. Throughout the day I was a[illegible]drinking another part of the herbalife plan called Herbal concentrate which is high in caffeine. While playing softball I went into cardiac arrest and had to be resuscitated 4 times. While in the emergency room the doctors kept asking family members and friends if I was using an inhaler or anything. I was a mystery to the hospital as to why I (a perfectly healthy 28 year old female) went into cardiac arrest. -(3)

I have never experienced anything like this in the past I have been playing sports for 20+ years and have never had to discontinue due to any medical problems other than sprains or broken bones. I now have to spend the rest of my life with a defribulator and adjust my entire life style. I am thankful that I still have my life.

I would like to, if possible help save another life by letting people know that there are serious side effects to this herb and I was lucky that there were two police officers on site or I wouldn't be here right now! I hope that this information can be used.

If you need to reach me or would like any additional information as to this situation please call me at [redacted] M-F 9:00 - 5:00 or after 5:00 PM
at [redacted]

Thank you for your time.

[redacted]

(1) Products were: Thermojetics Green w/maluang
(2) & Thermojetics Beige

3rd is "Herbal Concentrate"

- FU ok -

Info per telephone conversation
8/3/98 between [redacted]
& Kathleen Cheeseman
OSN/LRRS

COMPLAINT/INJURY FORM

1. COMPLAINT NUMBER: NWJ8-1041

2. DATE OF COMPLAINT (Month/Day/Year): 8/4/98

3. FORM OF COMPLAINT
(1) ☐ TELEPHONE
(2) ☒ LETTER
(3) ☐ VISIT

4. SOURCE OF COMPLAINT
(1) ☐ CONSUMER
(2) ☒ GOVERNMENT
(3) ☐ TRADE SOURCE
(4) ☐ OTHER
☐ S ☒ F (Indicate in Remarks)

5. COMPLAINANT IDENTIFICATION
a. NAME AND ADDRESS (Include Zip Code): [redacted]
b AREA CODE AND TELEPHONE NUMBER
HOME: [redacted]
WORK [redacted]

6. COMPLAINT OR INJURY
a. DESCRIPTION OF COMPLAINT/INJURY
Complainant's letter indicate that she went into "cardiac arrest" due to use of the product.

b. DOES COMPLAINANT EXPECT ADDITIONAL FDA CONTACT?
(1) ☐ NO (2) ☐ YES (Explain in Remarks)

7. INJURY OR ILLNESS RESULTED
(1) ☐ NO
(2) ☒ YES
(If "yes" complete items a through d)

a. EIB (HFC-161) NOTIFIED
(1) ☐ NO
(2) ☒ YES
DATE Mailed

b. TYPE SYMPTOM ONSET (HR.)
1 ☐ VOMITING
2 ☐ NAUSEA
3 ☐ DIARRHEA
4 ☐ FEVER
5. ☐ SKIN/EYE IRR.
6. ☐ HEADACHE
7 ☒ OTHER
Cardiac Arrest

c. ATTENDING HEALTH PROFESSIONAL
(1) ☐ NO (2) ☒ YES
(If "yes" give name, address, and phone number)
Dr. [redacted]

d. HOSPITALIZATION REQUIRED
(1) ☐ NO (2) ☒ YES
(If "yes" give name, address, phone number and dates)
[redacted]

8. PRODUCT AND LABELING
a. BRAND NAME: Herbalife
b PRODUCT NAME: Diet Supplement
c. SIZE AND PACKAGE TYPE: 2 sample packages
d. NAME AND LOCATION OF STORE WHERE PURCHASED:
e PACKAGE CODE/SERIAL NUMBER/ETC.
EXP/USE BY DATE
f. DATE PURCHASED: 5/27/98
g. PRODUCT USED (If "yes" enter date) 5/28/98
(1) ☐ NO (2) ☒ YES
h. AMT REMAINING: 1 sample package

9. MANUFACTURER/ DISTRIBUTOR OF PRODUCT
a HOME DISTRICT: A
b C F NO.: 2022908
c. NAME AND LOCATION OF FIRM (Include Zip Code): [redacted]
d. IMPORT PRODUCT
(1) ☒ NO
(2) ☐ YES

10. EVALUATION AND DISPOSITION
a. PROBLEM KEYWORD
(1) CODE: RX (2) DESCRIPTION: HEARTATTAC

b. EVALUATION
(1) ☐ NOT AN FDA OBLIGATION
(2) ☐ OBLIGATION, NO VIOLATION
(3) ☒ FDA ACTION INDICATED
(4) ☐ INSUFFICIENT INFORMATION UNABLE TO EVALUATE

c. DISPOSITION
(1) ☒ IMMEDIATE FOLLOW-UP
(2) ☐ F/U NEXT E1
(3) ☐ CLOSED WITHOUT FURTHER INVESTIGATION
(4) ☐ REFERRED TO OTHER FEDERAL AGENCY (Closes File)
(5) ☐ REFERRED TO STATE/LOCAL AGENCY (Closes file)
(6) ☐ REFERRED TO OTHER FDA DISTRICT

11. PRODUCT CODE: 60CBA21

12. INFORMATION COPIES TO:
☐ HFB-100 ☐ HFZ-343
☐ HFD-730 ☒ HFC-161
☐ HFV-236 ☒ HFS-635, LOS-DO

REMARKS
Complaint was sent in as request by CFSAN Complaint works at [redacted]. Complainant was initially taken to [redacted] then transferred to [redacted] As per CFSAN request, visit Complainant, collect remaining sample, complete adverse reaction questionnaire, collect medical records. Send sample to SEA-DO Laboratory for analysis of Ephedra Alkaloids.

98-11237
08/05/98
pg 1 of 1 EAN

NAME AND TITLE: Ms. Emma A. Nesbit, CCC

98 OCT 20 P1:30

DATE: 8/4/1998

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REVIEW/OSN HFS-452

FORM FDA 2516 (1/90)

000003

COMPLAINT . INJURY FOLLOW-UP

1. COMPLAINT NUMBER: NWJ8-1041

2.a. ACTION REQUESTED
- (1) ☒ INVESTIGATION
- (2) ☒ COLLECT SAMPLE
- (3) ☐ INSPECTION
- (4) ☐ OTHER.

2.b. REMARKS *(Additional Details)*
Visit Complainant, collect sample, complete affidavit, complete adverse reaction questionnaire, obtain medical records disclosure forms & collect medical records Send sample to SEA-DO Laboratory for analysis for Ephedrine Alkaloids.

2.c. REQUESTING OFFICIAL'S NAME AND TITLE	2.d. DATE REQUESTED	2.e. PROUCT NAME
Ms. Emma A. Nesbit, CCC	8-4-98	Herbalife Dietary Supplement

3.a. ASSIGNED TO:	3.b. DUE BY:	4.a. ACTION TAKEN	4.b. SAMPLE NUMBER(s)
Ms. Emma A. Nesbit		(1) ☒ INVESTIGATION (2) ☒ SAMPLE COLLECTED (3) ☐ INSPECTION (4) ☐ NONE	98-11237

4.c. DESCRIPTION OF ACTION TAKEN

On 8/5/98, I visited the workplace of the complainant, Ms. [redacted] located at [redacted] I presented my credentials and explained the nature of my visit. I asked her to recount the details of her problem with the dietary supplement.

Ms. [redacted] stated that on 5/27/98 a friend gave her two sample packages of Herbalife Thermojentic (green/beige) tablets plus one 1 8 oz bottle of Herbalife Thermojetcs Herbal Concentrate At approx 10:10a m. on 5/28/98, she consumed one beige and three green tablets as instructed by her friend. She also consumed glasses of the hergal concentrate throughout the day At approx 3 00 p.m. the same day, she consumed the remaining green and beige tablets from the package. During the day she could feel her hearet racing. After work, she went to the ballpart to play softeball. During the second game she collasped on the field and went into cardiac arrest. According to the [redacted], she was revived four times before they she was stable to be transported to [redacted] She was moved from [redacted] to [redacted] Since her release she has been regularly examined by Dr [redacted]

Ms [redacted] signed Authorization for Medical Records Disclosure Forms to obtain copies of her medical records. She alos supplied us with samples of the tablets and herbal concentrate powder.

I then went to both hospitals and the doctor's office to request copies of Ms. [redacted] medical records.

Sample were sent to SEA-DO Laboratory for analysis as requested by CFSAN.

4.d. ACTION OFFICIAL'S NAME AND TITLE	4.e. ACTION DISTRICT	4.f. DATE COMPLETED
Ms Emma A. Nesbit	T	8/5/98

5. MANUFACTURER/DISTRIBUTOR/DEALER RESPONSIBLE

5.a. HOME DIST.	5.c. NAME AND ADDRESS	6. PROGRAM DATA			
A	Herbalife International of America 9800 LaCienega Blvd. Los Angeles, CA 90080	6.a. OPERATION: 13	6.b. PAC: 46R801	6.c. PRODUCT CODE: 60CBA21	
5.b. CF NO.: 2022908		6.d. EMP. HOME DIST.: T	6.e. EMP. NO.: 274	6.f. POS CL.: 2	6.g. HOURS: 8 h

7. EVALUATION
- (0) ☐ PENDING
- (1) ☐ NO ACTION INDICATED (NAI)
- (2) ☐ VOLUNTARY ACTION INDICATED (VAI)
- (3) ☐ OFFICIAL ACTION INDICATED (OAI)
- (4) ☐ NOT AN FDA OBLIGATION
- (5) ☐ REFERRED TO HOME DISTRICT
- (6) ☐ INSUFFICIENT INFO UNABLE TO EVAL.
- (7) ☐ REFERRED TO OCI

8. FINAL DISPOSITION
- (1) ☐ FOLLOW-UP NEXT E1
- (2) ☐ WARNING LETTER
- (3) ☐ CITATION
- (4) ☐ SEIZURE
- (5) ☐ INJUNCTION / PROSECUTION
- (6) ☐ REFERRED TO OTHER AGENCY
  (Indicate Agency in **Remarks***)*
- (7) ☐ RECALL
- (8) ☐ NO ACTION

9. INFO. COPIES TO:
- ☐ HFB-100
- ☐ HFD-730
- ☐ HFV-236
- ☐ HFZ-343
- ☐ HFC-161
- ☐ HFS-635
- ☐
- ☐
- ☐
- ☐
- ☐
- ☐
- ☐

REMARKS

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NAME AND TITLE OF DISPOSITION OFFICIAL	DISPOSITION	DISPOSITION DATE

FORM FDA 2516a (3/94)

Adverse Reaction Information Form A

Complaint Number: NNJ8-1041 Investigator: Ms. Emma A. Nesbit

Consumer Information

Date of Report: 8/5/98 (MM/DD/YY)

Initial Report Source: ☒ORA Consumer Injury
☐Telephone ☒Correspondence ☐MedWatch
☐USP ☐PQRS ☐Poison Control ☐CDC

Name: Ms. [redacted] Gender: ☒F ☐M Age: 28

Race: ☒1-White ☐2-Black ☐3-Asian/Pacific Islander ☐4-Native American ☐5-Hispanic
☐8-Other _____ ☐9-Unknown

Information on Adverse Reaction

Date of Adverse Reaction: 5/28/98
Previous Reaction to Product Type: ☐Yes ☒No

Give the site of consumption/ingestion (e.g. home, restaurant, office): Softball Field

Describe the adverse event (including symptoms and the time lapse from using product to onset of symptoms):
Approx. 1 hr after initial use complainant experienced heart racing. 7 hrs later she went into cardiac arrest.

How long did the symptoms last? 2 weeks

Give the circumstances of exposure (e.g., dose, route of exposure, frequency, etc.).
4 tablets orally twice a day, five hours apart

List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used at the time of the event:
NONE

Did event abate after use of suspected product stopped or dose reduced: ☒Yes ☐No ☐Unknown
Did symptoms reoccur after reintroduction of suspected product: ☐Yes ☐No ☐Unknown ☒Not Applicable
Did symptoms reoccur after using other products with the same ingredients: ☐Yes ☐No ☐Unknown ☒Not Applicable

Medical Information

Was a health care provider seen?: ☒Yes ☐No
Give health care provider's name, address and telephone number:
Dr. [redacted]

Occupation of Health Care Provider: ☒MD ☐Osteopath ☐Naturopath ☐Nurse ☐Pharmacist
☐Other (specify) _____

What medical tests were performed and what were the results?

What was the medical diagnosis? Cardiac Arrest
What treatment(s) was given (e.g., drugs, other)? Surgery
Complainant is currently taking 25 mg tablets of Atenolol

Were there any preexisting condition(s)/treatment(s)?
(If YES, list them including allergies, and chronic diseases): ☐Yes ☒No

Product Category

1. Adverse reaction to:
   ☐**Medical Food** (under medical supervision) ☐**Infant Formula**
   ☒**Dietary Supplement** (a vitamin; an essential mineral, a protein a herb or similar nutritional substances including botanicals such as ginseng and yohimbe; amino acids, extracts from animal glands; garlic extract; fish oils, oil of evening primrose; fibers such as psyllium and guar gum; compounds not generally recognized as food or nutrients, such as bioflavonoids, enzymes, germanium, nucleic acids para-amino-benzoic acid, and rutin; and mixtures of these ingredients.)
   ☐**Other** (traditional food) _____

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Other Product Problems

2. ☐Foreign Object (specify): _____

3. ☐Other (specify): _____

Information on Suspected/Alleged Product

Give the product name (including dose/serving size, duration of use, and reason for taking):
Herbalife Thermojetics herbal tablets. Upon initial use complainant ingested 1 beige & 3 green tablets. Product was taken at 10:00 a.m. & 3:00 p.m. She also consumed 1/2 teaspoon of Thermojetics Herbal Concentrate in approx 8 oz of water throughout the day. She consumed these products as a method of weight loss.

List product ingredients (if ingredients are suspected to be present, but not verified, list as suspected):

☐Check here if ingredients are unknown

Green Tab. - Chinese Ma Huang, Bladderwrack, Yerba Mate', Valerian Root etc

Beige Tab. - Hawthorn Berry, Alfalfa, Parsley, Marshmallow Root, etc.

Herbal Concentrate - Camellia sinensis (green tea & orange pekoe tea etc.

If a particular ingredient is suspected of contributing to the reaction, please indicate the appropriate category below:

☐Aspartame
☐Monosodium Glutamate
☐Sulfite
☒Other Ephedra
☐Unknown

☐Color Additive (please specify) _____

Product Label Available: ☒Yes ☐No ☐Unknown Product Sample Available: ☒Yes ☐No ☐Unknown

Outcome Attributed to Adverse Event:

(If yes, include pertinent medical records)

Death: ☐Yes ☒No

Life-Threatening: ☒Yes ☐No

Hospitalization: ☒Yes ☐No (if YES, indicate if initial or prolonged) prolonged

Required intervention to prevent permanent impairment/damage: ☒Yes ☐No

Did the adverse reaction result in a congenital anomaly: ☐Yes ☒No

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